UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
THIS DOCUMENT RELATES TO: ALL CLASS ACTIONS	CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris

PLAINTIFFS' MEMORANDUM IN SUPPORT OF A) THEIR MOTION TO STRIKE THE PORTIONS OF THE SCHERING-PLOUGH GROUP'S OPENING STATEMENT REFERENCING ASPs FOR SCHERING-PLOUGH GROUP DRUGS AND B) THEIR MOTION *IN LIMINE* TO PRECLUDE THE INTRODUCTION BY THE SCHERING-PLOUGH GROUP OF EVIDENCE OF ASPs FOR SCHERING-PLOUGH GROUP DRUGS

During their opening statement at the currently ongoing trial regarding Class 2 and Class 3 issues, Schering-Plough Corporation's ("Schering") and Warrick Pharmaceuticals Corporation's ("Warrick") (collectively, "the Schering-Plough Group") referenced average sale prices ("ASPs") for their branded and generic albuterol products. According to the Schering-Plough Group, the evidence purportedly shows that when in 2005 Medicare Part B began reimbursing for albuterol on the basis of ASP plus a dispensing fee, Medicare Part B actually began paying more for albuterol overall than it was paying under the AWP-based reimbursement system. This purported evidence, according to the Schering-Plough Group, means that Class 2 and Class 3 plaintiffs were not damaged by Schering's and Warrick's AWP-related behavior. But for the AWP-based reimbursement system, the theory goes, plaintiffs actually would have been paying *more* for albuterol all along.

Aside from the basic speciousness of the argument, which rests on a host of faulty assumptions, including the self-serving assumption that there were and are only two ways to reimburse for drugs — the AWP-based system as abused by the defendants and the ASP-plus-fee-based system as configured in 2005 and 2006[1] — the argument cannot be maintained without being able to show the ***after*** in Schering and Warrick's before-and-after matrix. And showing the ***after*** requires the presentation of ASPs; otherwise, there is no way to demonstrate that the ASP-based system resulted in greater reimbursement outlays than the AWP-based system, if that were indeed the truth.

The problem for the Schering-Plough Group, however, is that it cannot now introduce evidence of, or rely upon, ASPs for its drugs as a means of defending this case. The simple reason is that Schering and Warrick refused to produce to plaintiffs evidence as to such ASPs ***before*** trial, when they should have, during the discovery process.

On May 26, 2004, plaintiffs propounded their Request for Production to Defendants Regarding HHS ASPs. (Declaration of Robert F. Lopez in Support of Plaintiffs' A) Motion To Strike and B) Motion *in Limine* ("Lopez Decl."), Ex. A.) In pertinent part, those requests for production sought "[a]ll documents showing ASPs or ASP information you have provided for any AWPID pursuant to the Interim Medicare Regulations [which term was defined]." (*Id.* at p. 1.)

[1] The Schering-Plough Group apparently had a hand in the establishment of the ASP-plus-fee-based system it now seeks to attack as more expensive than the AWP-based system it replaced. As plaintiffs understand it, the Schering-Plough Group lobbied with regard to the way in which the ASP-plus-fee-based system would be configured. Insofar as the Schering-Plough Group contributed to the establishment of the ASP-plus-fee-based system it now decries as more expensive than the previous system, it should be estopped or otherwise prevented from using against the plaintiffs in this trial the very details it helped to procure.

Schering and Warrick refused to produce the requested documents and information. In addition to stating several general objections to production, Schering and Warrick specifically responded to the request for ASP-related documents and information as follows:

> In addition to the General Objections set forth above, Schering [collectively referring to Schering and Warrick] objects to Request No. 1 on the grounds that it is overly broad and that responding to the request as stated would be unduly burdensome. Schering further objects to Request No. 1 on the ground that it calls for documents that are irrelevant and unlikely to lead to the discovery of admissible evidence. Specifically, Schering objects to the request to the extent it calls for documents "provided . . . pursuant to the Interim Medicare Regulations." Schering further objects on the ground that the terms "ASP" and "ASP information" and the phrase "you have provided for any AWPID" are vague and ambiguous.

(Lopez Decl., Ex. B at pp. 3-4.)

Thereafter, plaintiffs moved to compel. At the September 27, 2004 hearing on the motion, defendants, including the Schering-Plough Group, resisted plaintiffs' motion, arguing in part that the federal government's regulations regarding ASPs were "moving targets," and that the "net effect" of ongoing changes to the regulations rendered the first submittals of ASPs to the federal government "totally meaningless." (Lopez Decl., Ex. C at pp. 15-28.) Defendants also argued that plaintiffs simply should use the data that defendants had supposedly provided them "to perform [an] historical average selling price model if they choose to do that as part of their case." (*Id.* at pp.16, 25-26.) And defendants argued that "the average selling price requirement deals with quarters that are not at issue in the plaintiffs' amendment [sic] consolidated complaint," even though defendants acknowledged having prepared and reported ASPs for two quarters in 2004 as of the time of the argument (*id.* at pp. 15, 21-22) — time periods that were covered by the amended consolidated complaint.

The Court denied plaintiffs' motion to compel, and defendants did not produce the requested information to the plaintiffs. Having refused to produce ASP-related documents and

information to plaintiffs during discovery, the Schering-Plough Group cannot now use such documents and information against the plaintiffs at trial. *Telewizja Polska USA, Inc. v. Echostar Satellite Corp.*, 2004 U.S. Dist. Lexis 20845, at *6 (N.D. Ill. Oct. 14, 2004) ("The Court agrees that Defendant should not be permitted to introduce evidence at trial that it refused to produce during discovery."); *Conopco, Inc. v. Warner-Lambert Co.*, 2000 U.S. Dist. Lexis 1605, at *39 (D.N.J. Jan. 24, 2000) ("To the extent that defendants shall rely on the defense of invalidity due to obviousness, defendants will produce documents related to 'copying' and 'designing around' in that these are related to the validity of the patents-in-suit. ***If defendants do not produce such information, they will not be permitted to introduce it as evidence later***.") (emphasis added).

To permit the Schering-Plough Group to refer to and rely upon evidence of ASPs for their drugs in their defense of this case at trial, especially where Schering and Warrick made a specific choice not to produce ASP-related material in discovery, would be to countenance trial by ambush. And trial by ambush is not permitted under the Federal Rules of Civil Procedure or by the decisions of the court of appeals. *E.g.*, *Klonoski v. Mahlab*, 156 F.3d 255, 271 (1st Cir. 1998) ("The purpose of the discovery rules is to provide for the 'fullest possible' pretrial disclosure of admissible evidence, to 'reduce the possibility of surprise," . . . and to insure 'a fair contest . . . ." As the court went on, "We have recently condemned trial by ambush tactics and for this reason vacated a verdict returned for the defendant.") (citations omitted).

For these reasons, plaintiffs pray respectfully that the Court strike all references made by the Schering-Plough Group in their opening statement to the ASPs for their drugs, including branded and generic albuterol. Plaintiffs also pray respectfully that the Court issue an order *in limine* precluding the Schering-Plough Group from relying upon at trial, or introducing evidence

at trial referencing or relating to, the ASPs for their drugs, including branded and generic albuterol.

DATED: November 13, 2006

By **/s/ Steve W. Berman**

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CERTIFICATE OF SERVICE

I hereby certify that I, Steve W. Berman, an attorney, caused a true and correct copy of the foregoing **PLAINTIFFS' MEMORANDUM IN SUPPORT OF A) THEIR MOTION TO STRIKE THE PORTIONS OF THE SCHERING-PLOUGH GROUP'S OPENING STATEMENT REFERENCING ASPs FOR SCHERING-PLOUGH GROUP DRUGS AND B) THEIR MOTION IN LIMINE TO PRECLUDE THE INTRODUCTION BY THE SCHERING-PLOUGH GROUP OF EVIDENCE OF ASPs FOR SCHERING-PLOUGH GROUP DRUGS** to be delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on November 13, 2006, a copy to LexisNexis File & Serve for posting and notification to all parties.

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